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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/142,557 09/11/98 PILARSKI

L P-1459(0)

HM22/0509

EXAMINER

FONDA, K

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SUITE 200
THORNHILL ON L3T 7P6
CANADA

ART UNIT

PAPER NUMBER

1623

AIR MAIL

DATE MAILED:

05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/142,557	Applicant Pilarski
	Examiner Kathleen Kahler Fonda	Group Art Unit 1623

☒ Responsive to communication(s) filed on 3-13-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 94 and 101-170 is/are pending in the application.

Of the above, claim(s) 94, 101, 102, 104, 105, 112, 113, 127-129, 137, 140, 142 and 145-170 are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's election with traverse of Group IV, claims 103, 106-111, 114-124, 130, 131, 133-136, 138, 139, 141, 143, and 144 in Paper No. 8 is acknowledged. The traversal is on the grounds, stated in Paper No. 5, that stem cells of Group VII and red blood cells of Group X are encompassed by hematopoietic cells of Group IV. This argument is persuasive, and the Examiner hereby rejoins Group VII, claims 125, 126, and 133-136, and Group X, claims 132-136, to Group IV. Thus the pending claims are 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144.

Applicant has not presented any arguments as to why the restriction should not be maintained as to the other groups. The restriction requirement with regard to Groups I-III, V, VI, VIII, IX, and XI-XIV is still deemed proper and is therefore made FINAL.

The Drawings are approved by the Draftsperson.

An Information Disclosure Statement has been submitted, but no copies of the cited references are present in the file. Applicant should provide copies for the Examiner's consideration.

Applicant is requested to clarify the priority information. Page 1 of the specification should be amended to recite the

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national stage entry under 35 U.S.C. § 371, as well as any domestic priority claimed.

Applicant is advised that should claim 111 be found allowable, claim 131 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Applicant may avoid this objection by rephrasing claim 131 to recite a method of modulating symptoms of allergy or asthma.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 103, 106-111, 114-126, 130, 131, 133-136, 138, 139, 141, 143, and 144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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Claims 103 and 116 lack positive antecedent basis for "the stimulation" and are therefore indefinite.

Claim 103 is indefinite because the phrase "enhancing the stimulation of cells production/release" does not particularly point out that which Applicant intends to claim.

Claim 103 is indefinite because it fails to recite to whom or to what the hyaluronic acid is to be administered.

Claims 103, 111, 139, and 141 are indefinite because the phrase "effective amount" has no particular art-recognized meaning and has not be adequately defined in the specification.

Claim 111 lacks positive antecedent basis for "the administration" and is therefore indefinite.

Claim 111, by its preamble, is drawn to a method for administration of hyaluronic acid. Claim 112 is indefinite because it fails to recite any steps of such a method.

Claim 111 is indefinite because it is not clear what Applicant intends to claim by the recitation of "enhancing, stimulating and releasing . . . cells . . . into the blood".

Claim 116 is indefinite because the term "predetermined intervals" has no particular art-recognized meaning, and has not been adequately defined in the specification.

Claims 124 and 125 are indefinite because the phrase "treating a patient for" would seem to require a disorder as the object of "for", and Applicant actually recites "mobilizing

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hematopoietic cells", which is a desirable phenomenon. Applicant may wish to consider reciting --treating a patient in order to mobilize hematopoietic cells--.

Claims 126 lacks positive antecedent basis for "the peripheral blood", and is therefore indefinite.

Claim 136 is indefinite because it lacks positive antecedent basis for "the form of hyaluronan" in lines 2 and 3. The Examiner also notes that because claim 136 depends from claim 133, sodium hyaluronate must be administered in claim 136.

Claims 138 and 139 lack positive antecedent basis for "the infusion", and are therefore indefinite.

Claim 139 and 141 are indefinite because they lack any steps of the claimed methods.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144 are rejected under 35 U.S.C. 103(a) as being unpatentable

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over either HAMANN *et al.* (K) or HAN *et al.* (L), in view of FALK *et al.* (A).

Applicant claims methods of stimulating production or release of hematopoietic or dendritic cells, including stem cells or red blood cells, by administering hyaluronic acid.

HAMANN teaches that hyaluronic acid stimulates growth of megakaryocyte progenitors; see, for example, the Abstract. HAMANN also specifically refers to implications for treatment of asthma; see the first paragraph following the Abstract.

HAN teaches that hyaluronic acid stimulates growth of CD34+ selected umbilical cord blood cells into specifically differentiated mature eosinophils; see, for example, the Abstract. HAN also states that this property of hyaluronic acid could be clinically useful for management of thrombocytopenias; see the last paragraph on page 103.

Neither HAMANN nor HAN explicitly teaches administering hyaluronic acid to a patient.

FALK teaches that hyaluronic acid may be to patients administered for various therapeutic purposes, in amounts and molecular weight which encompass those of the claims; see column 15, lines 44-49, the claims, and the Examples. FALK also teaches administration of multiple doses at time intervals; see column 10, lines 46-50.

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It would have been obvious for a person of ordinary skill in the art at the time of the invention to administer hyaluronic acid to a patient in order to stimulate production or release of hematopoietic or dendritic cells, including stem cells or red blood cells. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because each of HAMANN and HAN had taught that hyaluronic acid had the activity recited by Applicant, and each had suggested its therapeutic potential. FALK had confirmed that hyaluronic acid could be used therapeutically. No criticality or unexpected result is seen to stem from any specific molecular weight or dosage of the claims, or from multiple doses. These specifics of administration would have been obvious in view of the teaching of FALK.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

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INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://pto-ebc.uspto.gov> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached on Monday and Friday afternoons, and on Tuesday and Thursday mornings. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Gary Geist at (703) 308-1701. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D.
Primary Examiner
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